

REMARKS

Claims 1 and 3-6 are pending in this application. Claim 7 has been canceled without prejudice or disclaimer. Claim 1 has been amended.

Claim 1 has been amended to incorporate the limitations of claim 7, now cancelled. Support for the amendment is found in the specification as-filed, for example, at page 11, line 18, to page 12, line 5, and in the Examples. These amendments are for the sole reason of advancing prosecution. Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the subject matter canceled herein or the original claim scope of any claim amended herein, in a continuing application.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

I. Rejection of claim 1 under 35 U.S.C. §102(b)

The Official Action states that the rejection of claim 1 under 35 U.S.C. §102(b) of March 4, 2008, over Hoffman et al. "has been **withdrawn**," (emphasis added). However, the Official Action also indicates that Applicants' arguments in the previously filed response "have been fully considered and are **not** persuasive," (emphasis added). Since the rejection has not been reiterated, it would appear that the rejection has been withdrawn as indicated. Accordingly, Applicants' respectfully request clarification of

whether the rejection has been withdrawn or if it is being maintained.

II. Rejection of claims 2 and 3 under 35 U.S.C. § 103(a)

The Official Action states that claims 1 and 3-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Miranda et al. (U.S. Patent No. 5,656,286), in view of Hoffmann. In particular, the Official Action in relevant part states that:

Miranda teaches a transdermal drug delivery system "wherein a blend of at least two polymers...permits increased loading of a drug and adjusts the solubility of a drug in the blend and thereby modulates the delivery of the drug from the system and through the dermis" (Col. 2, lines 51-57). Since Zmiranda teaches the drug in the polymeric adhesive system (Col. 1, lines 24-34), one with ordinary skill in the art would know that the drug is in a single layer with the blend of polymers....

Applicant argues that the Hofman reference teaches away by disclosing patch formulations where the layer structure and the combination of componenets in the layer(s) are different from those recited in the presently pending claims.

This is not persuasive.... Hoffman cures the deficiency of Miranda and is used as supporting reference that provides the teaching of self-crosslinking acrylate copolymer of 2-ethyl-hexyl acrylate and vinyl acetate in a transdermal therapeutic system (Col. 7, lines 1-8).

Applicants respectfully traverse the rejection of claims 1 and 3-7 for the reasons of record, and as supplemented herein. The cited references do not establish a *prima facie* case of obviousness against the presently pending claims. To establish a *prima facie* case of obviousness, three requirements must be satisfied. First, as the U.S. Supreme Court recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U.S. (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple

patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR*, supra, slip opinion at 13-15). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ 1016, 1023 (C.C.P.A. 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

A. The Presently Claimed Invention

The presently pending claims as exemplified by presently pending independent claim 1, are directed to:

A patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with a drug and an adhesive base agent, wherein the adhesive base agent comprises styrene-isoprene-styrene block copolymer, 2-ethylhexyl acrylate – vinyl acetate copolymer and a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature selected from the group consisting of methyl methacrylate – butyl methacrylate – dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate, and wherein the weight ratio of the content of the

styrene-isoprene-styrene block copolymer to 2-ethylhexyl acrylate – vinyl acetate copolymer is from 1:1 to 9:1.

Dependent claims 3-6 each incorporate the features recited in independent claim 1, and further recite the features of: the drug, pergolide; the use of an organic acid in the adhesive layer; the use of an alicyclic saturated hydrocarbon-based tackifier in the adhesive layer; the weight ratio of the content of the styrene-isoprene styrene block copolymer to the content of the 2-ethyl-hexyl acrylate vinyl acetate copolymer, respectively; and wherein the weight ratio of the content of the styrene-isoprene-styrene block copolymer to 2-ethylhexyl acrylate – vinyl acetate copolymer is from 1:1 to 9:1.

Moreover, Applicants point out that the data shown in Tables 1-4 on pages 34-37 of the present specification demonstrates the unexpectedly superior results achieved by the presently claimed patch formulations as compared to patch formulations lacking one or more of the copolymers recited in the presently pending claims, and therefore, the present claims are non-obvious over the applied references.

B. The Teachings of the Miranda et al. Reference

The Miranda et al. reference describes “a transdermal drug delivery composition wherein a blend of polymers is utilized to affect the rate of drug delivery from the composition.” See Miranda et al., column 1, lines 26-28.

C. The Teachings of the Hoffmann Reference

The Hoffmann reference describes “a novel therapeutic system with active substance depot for the administration of the active substance.” See Hoffmann, column

2, lines 37 and 38.

D. No *prima facie* Case of Obviousness Has Been Shown

Neither the Miranda et al. nor the Hoffmann references, taken alone or in combination, disclose all of the limitations of the presently pending claims, as required by *In re Wilson*. Neither the Miranda et al. nor the Hoffmann references either taken alone or in combination describe the weight ratio of the content of the styrene-isoprene styrene block copolymer to the content of the 2-ethyl-hexyl acrylate vinyl acetate copolymer, respectively; and wherein the weight ratio of the content of the styrene-isoprene-styrene block copolymer to the 2-ethylhexyl acrylate – vinyl acetate copolymer is from 1:1 to 9:1. There is no suggestion in the art to modify the combination of references to achieve the recited ratio. Accordingly, a *prima facie* case of obviousness has not been established.

E. Unexpected Results Overcome *Prima Facie* Case

Even if the Examiner continues to assert that a *prima facie* case of obviousness has been shown, Applicants provide evidence of unexpected results of the claimed composition to rebut the assertion of a *prima facie* case of obviousness.

The Examiner asserts that

[T]he limitation of the weight ratio of the content of the styrene-isoprene-styrene block copolymer to the content of the 2-ethyl-hexyl acrylate vinyl acetate copolymer would have been obvious over the teaching by Miranda that by varying the amount of each type of monomer added, the cohesive properties of the resulting acrylate polymer can be changed as is known in the art' (Col. 10, lines 51-54). Therefore, one with ordinary skill in the art would modify the ratio of the styrene-isoprene-styrene block copolymer

to the content of the 2-ethyl-hexyl acrylate vinyl acetate copolymer during the process of routine experimentation, and ***the recited ratio would have been an obvious variant unless there is evidence of criticality or unexpected results.***

Emphasis added.

Applicants bring the Examiner's attention to the unexpectedly superior properties of the presently claimed matrix outlined in Tables 1-4 on pages 34-37 of the instant specification which demonstrates the unexpectedly superior results achieved by the presently claimed patch formulations as compared to patch formulations lacking one or more of the copolymers recited in the presently pending claims. In particular, Examples 1-3 summarized in Table 1 and Examples 4-7 in Tables 3-4 show adhesion and cohesion properties for compositions containing the presently claimed components. Comparative Examples 1-22 in Tables 1-4 show adhesion and cohesion properties for compositions lacking at least one of the components of the presently claimed formulation. ***The data clearly shows superior patch properties, when compared to the patch properties for compositions lacking at least one of the claimed components.***

Furthermore, Applicants provide the attached expert's declaration of Kazunosuke Aida, which provides supplemental experimental evidence showing the unexpectedly superior results for the patch cohesion property when the weight ratio (A:B) of the content of the styrene-isoprene-styrene block copolymer (A) to 2-ethylhexyl acrylate – vinyl acetate copolymer (B) is from 1:1 to 9:1. Comparative Example A is directed to the same composition for Example 1-3, except that its A:B ratio is 4:6, which is outside

the 1:1 to 9:1 range recited in the present claims. See Appendix A of attached expert's declaration. Examples 1-3 and comparative example 1 show the same measurements provided in the specification in Table 1, on page 34. Clearly, patch examples 1-3, having an A:B ratio of 1:1 to 9:1, have an unexpectedly superior Cohesion properties as compared to Comparative Example A having an A:B ratio of only 4:6, which is outside the 1:1 to 9:1 range recited in the present claims.

Accordingly, the results outlined in Tables 1-4, on pages 34-37, of the instant specification, and the results in the attached expert's declaration, show unexpectedly superior results for the presently claimed compositions. Moreover, there is **no** teaching or suggestion in the cited combination of references that one of ordinary skill in the art would have had a reasonable expectation of successfully combining the teachings of Miranda et al. with the teachings of Hoffman et al. to devise the claimed unexpectedly superior patch.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the present rejection.

III. Provisional Rejection of Claim 1 under the Judicially Created
Doctrine of Obviousness-Type Double Patenting

The final Official Action states that claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8 and 12 of copending U.S. Patent Application Serial No. 10/469,612.

The Examiner asserts that although the conflicting claims are not identical, they

are not patentably distinct from each other. The Examiner notes that the instant claims are directed to a patch comprising a backing layer and an adhesive layer that is compounded with a drug and an adhesive base agent. The Examiner asserts that the claims of the co-pending application no. 10/526,065 also describe a patch comprising a backing layer and an adhesive layer compounded with an adhesive agent and pergolide.

It is submitted that present claims 1 and 4-6 are patentably distinct from the claims of co-pending application no. 10/526,065. With regard to claims 1 and 4-6 of the instant application, all of claims 1 and 4-6 are directed to a patch formulation where the adhesive layer contains a drug; styrene-isoprene-styrene block copolymer; 2-ethylhexyl acrylate-vinyl acetate copolymer; and a basic nitrogen-including polymer including a basic nitrogen and having no adhesion property at normal temperature selected from the group consisting of methyl methacrylate-butyl methacrylate-dimethylaminoethyl methacrylate terpolymer and polyvinyl acetal diethylamino acetate, and wherein the weight ratio of the content of the styrene-isoprene-styrene block copolymer to 2-ethylhexyl acrylate – vinyl acetate copolymer is from 1:1 to 9:1. Claims 1-11 of co-pending application no. 10/526,065 do not recite the specific combination of components in the adhesive layer that are required by pending claims 1 and 4-6 of the instant application. Accordingly, present claims 1 and 4-6 are patentably distinct from claims 1-11 of co-pending application no. 10/526,065. The Examiner is respectfully requested to withdraw this rejection of pending claims 1 and 4-6.

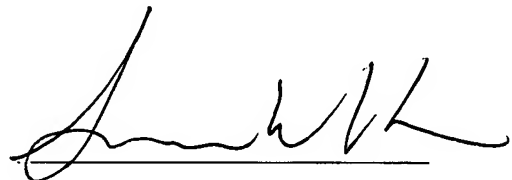
CONCLUSION

Applicants submit that the application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

In the event this paper is not timely filed, Applicants hereby petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

Date: December 19, 2008

A handwritten signature in black ink, appearing to read 'Gary M. Nath', is written over a horizontal line.

Gary M. Nath
Registration No. 26,965
Joshua B. Goldberg
Registration No. 44,126
Susanne M. Hopkins
Registration No. 33,247
Customer No. 20529

THE NATH LAW GROUP, PLLC
112 South West Street
Alexandria, VA 22314
Phone: (703)548-6284